Time Critical Diagnosis—Stroke and STEMI System Implementation
November 17, 2009 Meeting Highlights

ATTENDEES:

Dr. Samar Muzaffar, Department of Health and Senior Services (DHSS); Debra Abbott, North Kansas City Hospital; Tony Adams, HCA Midwest Healthcare; Tricia Adams, Audrain Medical Center; Paula Adkison, DHSS; Mark Alexander, CoxHealth; Kristi Baden, Boone Hospital Center; Dr. Conrad Balcer, St. Mary's Health Center; Lynn Barrett, Centerpoint Medical Center; Steve Bassett, Ozark Medical Center; Carol Beal, St. John's Regional Health Center; Anita Berwanger, DHSS; Nancy Bettasso, St. John's Regional Medical Center; Lucy Bevill, Salt River Ambulance; Cherie Boxberger, American Heart Association; Peggy Brand, Genentech; Linda Brown, Southeast Missouri Hospital; Lori Brown, Skaggs Regional Medical Center; Chris Byrd, Southeast Missouri Hospital; Monti Callow, Southeast Missouri Hospital; Kent Cantrell, Excelsior Springs Fire Dept; Dr. W. Stephen Casady, Putnam County Hospital; Doug Clark, Hermann Area EMS; John Clemens, Marion County Ambulance District; Karen Connell, DHSS; Richard Cotter, Taney County Ambulance District; Rich Dandridge, Warren County Ambulance District; Susan Davis, St. John's Mercy Medical Center; Mary Davis, Skaggs Regional Medical Center; Linda Dean, Freeman Health System; Liz Deken, American Heart Association; Marcia Dial, Scotland County Memorial Hospital; Lisa Donnelly, St. Luke's Hospital; Joan Drake, Staff for Life Helicopter; David Durbin, SSM Health Care; Joan Eberhardt, Missouri Emergency Nurses Association; Ellen Ehrhardt, DHSS; Emily Featherston, Missouri Delta Medical Center; Kelly Ferrara, The Vandiver Group; Cindy Feutz, University of Missouri Hospital and Clinics; Chrissy Foster, Poplar Bluff Regional Medical Center; Linda Freymuth, Lincoln County Ambulance District; Dr. Brian Froelke, Washington University; Kim Geiger, Skaggs Community Health Center; Belva Giesing, St. Luke's East; Cindy Giliam, DHSS; Dale Green, PRN Healthcare Consultants; Paul Guptill, Missouri Hospital Association; Dr. David Gustafson, Medical Director; Carol Hafley, Missouri Center for Patient Safety; Jami Ham, Poplar Bluff Regional Medical Center; Belinda Heimericks, DHSS; Kathleen Henderson, St. Joseph Medical Center; Steve Henningsen, Toshiba; Rita Hess, Des Peres Hospital; Michael Hicks, Mid American Regional Council; Rob Hippe, Toshiba; Melinda Huenefeld, Lincoln County Medical Center; Lindy Huff, St. Luke's Hospital; Melissa Hunter, Lake Regional Hospital; Lisa Hutchison, St. John's Regional Health Center; Sandra Irwin, Skaggs Regional Medical Center; Stacey Jett, Boone Hospital; Martha Johnson, Boone Hospital Center; Tina Jones, Poplar Bluff Regional Medical Center; Freida Juliano, Hannibal Regional Hospital; Melissa Kaufman, Audrain Medical Center; Dr. George Kichura, St. John's Mercy Heart & Vascular; Tim Kimball, Ozark Medical Center; Darlean King, Lilly, USA; Shelleen King, St. Luke's Hospital of Kansas City; Mary Ann Kirkpatrick, St. John's Hospital; Leigh Kite, University Hospital and Clinics; Mary Kleffner, DHSS; Dr. Michael Klevens, St. Luke's Hospital; Ken Koch; St. Charles County Ambulance District; Sherry Kriegshauser, American Heart Assn; Carol Lacy, Salem Memorial Hospital; Michael Lambert, University of Missouri Health Care; Dennise Lawson, Ozarks Medical Center; Dr. Jin-Moo Lee, Department of Neurology, Washington University; Jennifer Lembeck, Sanofi-Aventis Pharmaceuticals; Katie Liberto, Physio-Control; Andy Likes, The Vandiver Group; Dr. Michael Lim, Saint Louis University; Dean Linneman, DHSS; Jeannie Looper, Ozark Medical Center; Dr. John Lucio, St. Mary's Health Center; Cathy Luebbert, Capital Regional Medical Center; Colin McCoy, St. Louis Fire Department; Bryant McNally, Missouri Hospital Association; Deborah Markenson, DHSS; Lisa Markham, Poplar Bluff Regional Medical Center; Jane Martin, Genentech; John Martin, Slater Ambulance District; Willie Maxwell, Lake Regional Hospital; Tiffany Means, St. John's; Chris Medlin, Capital Region Medical Center; Bill Meeker, Laredo Fire Department; Ruby Mehrer, Lifeflight Eagle; Darla Merideth, St. Joseph Hospital West and St. Joseph Health Center; Michele Meyer, Des Peres Hospital; Taz Meyer, St. Charles Ambulance District; George Miller, Boone County Fire Protection District; Michelle Miller, Missouri Foundation for Health; Joyce Miloro, Capital Regional Medical Center; Cynthia Miltenberger, Cass Regional Medical Center; Jason Moburg, North Kansas City Hospital; Jill Mowry, St. Louis University Hospital; Nancy Noedel, St. Louis University; Dr. Peter Panagos, Washington University; Peggy Parks, Northeast Regional Medical Center; Jennifer Parreira, Research Medical Center; Wally Patrick, Heartland Regional Medical Center; Dennis Peacock, Bristol-Meyer Squibb; Michelle Pearce, Des Peres Hospital; Janet Pestle, St. Mary's Health Center; Debbie Playter, Audrain Medical Center; Amy Plott, Skaggs Regional Medical Center; Regina Politte, Jefferson Regional Medical Center; Dr. Raana Ponstingl, Des Peres Hospital; Lorrie Pulliam, Cass Regional Medical Center; Dr. Keith Ratcliff, Missouri Academy of Family Physicians; Dr. Danelle Richards, St. John's Hospital-Lebanon; Lisa Riggs, St. Luke's Health System; Dr. Morton Rinder, St. Luke's Hospital; Connie Roberts, Putnam County Memorial Hospital; Dr. John Russell, Cape County Private Ambulance Service; Dr. Marilyn Rymer, St. Luke's Hospital; Kandi Sagehorn, ARCH-Air Methods; Dr. Joseph Salomone, Kansas City EMS/SAC; Twany Sandifer, Capital Region Medical Center; Helen Sandkuhl, St. Louis University Hospital; Cindy Scalise, St. Luke's Hospital; Barb Seagrass, Des Peres Hospital; Heather Seemann, Pulaski County Ambulance District; Jace Smith, American Heart Association; Melissa Smith, Boone Hospital Center; Andrew Spain, University of Missouri Hospital and Clinics; Edward Spain, St. John's Regional Health Center; Debby Sprandel, St. Francis Medical Center; David Stagner, St. Francis Medical Center; Chad Staley, Montgomery County Ambulance District; Mickey Stout, St. John's Hospital – Lebanon; Shari Terada, Lilly, USA; Dr. Charles Tillman, Audrain Medical Center; Michael Tonn, Sanofi-Aventis Pharmaceuticals; Dr. Alan Umbright, SSM St. Joseph; Laura Vandiver, The Vandiver Group; Marsha Van Nest, St. Anthony's Medical Center; Amy Vannier, HCA Midwest Healthcare; Kathy Vickery, Southeast Missouri Hospital; Brent Walker, St. Luke's East; Michael Wallace, Central Jackson County Fire Protection District; Myrna Ward, Southeast Missouri Hospital; Jim Waring, Wheeler Heart and Vascular Center; Terri Waters, The Vandiver Group; Denise Webber, St. Mary's Health Center; Marilyn Welling, St. John's Regional Medical Center; Jason White, Metropolitan Ambulance Service Trust; Dr. Ted Wilmore, St. Mary's Health Center; Karen Wilson, St. John's Aurora; Kari Wilson, Audrain Medical Center; Steve Woods, Des Peres Hospital; Monroe Yancie St. Louis Fire Department; Beverly Smith, DHSS.

General Information

A total 168 people attended the eighth meeting of the Time Critical Diagnosis (TCD) Stroke and STEMI System implementation process. Michelle Miller, Missouri Foundation for Health (MFH), welcomed the group and expressed appreciation for the extraordinary contributions that have been made by those participating in this meeting series to advance the TCD system. MFH provided lapel pins to acknowledge those attending and to help promote the concept to others.

Dr. Samar Muzaffar provided an overview of the activities and outcomes completed since the last meeting held on May 12, 2009. The overview of these activities and outcomes were summarized as a handout. (Attachment 1) The key activities that occurred over the summer-fall period included a statewide review of the trauma arm of the TCD system that was conducted by the American College of Surgeons/Committee on Trauma; a series of 10 meetings and conference calls to discuss and update regulation drafts; a series of six regional meetings to present

work completed to date; and an on-line survey to obtain formal feedback on the draft regulations after the regional meeting series was completed. Through the survey the Department received specific comments and an indication of satisfaction levels regarding each section of the stroke and STEMI regulations. A summary of the survey findings can be found on Attachment 2.

The timeline for the regulations was reviewed. It was planned that the draft would be done in December 2009 with administrative and legal reviews predicted to take an additional three months. When all administrative and legal reviews have been completed and the proposed regulations are approved by State of Missouri administration then they will be filed with the Secretary of State's Office for publication in the Missouri Register. Once published there will be at least a 30 day period for comments, after which, the Department has 90 days to review comments and make a determination if changes are warranted based on the comments. At that time, the final regulations are filed with the Secretary of State's Office along with formal responses to comments, and the rules become effective 30 days after filed. The very earliest the regulations would go into effect would be the end of 2010 but if there are delays anywhere along the process, this effective date may be delayed.

Regulation Discussion

The group then sub-divided into three groups to discuss the stroke and STEMI regulations and the transport protocols also proposed for regulations. A summary of changes made in regulations for each of the respective conditions and discussion points for the day were distributed. (Attachment 3) The Department made changes based on input that had been received and subsequent research. The STEMI regulation group reviewed the draft regulations with the following recommendations or changes:

STEMI

- Keep recommendation for 75 PCIs per operator;
- Maintain proposed volume standards for Level I and Level II STEMI centers and allow adequate time frame over which this should be measured, group increased this time frame from two to three years;
- Focus outcome and process measures on quality within a system and not on quantity;
- In medical staffing section, extend the cardiothoracic surgeon requirement from Level I to also include Level IIs that choose to perform surgery. Delete the hospitalist requirement for Level IVs;
- Approve proposed CME and continuing education hours and language clarification that was done regarding continuing education requirements;
- Remove requirement for emergency medicine specialty for the emergency department physician since there are a multitude of routes to become an emergency department physician and hospital can assure credentials; (also approved by stroke group)
- Approve definition added for cardiac rehabilitation; and
- Maintain four levels of STEMI Centers

Stroke

The stroke regulation group took the following actions:

- Modify CME and continuing education requirements to align Missouri standards with recommendations made by the Brain Attack Coalition;
- Require neurologist for stroke program medical director only at Level I centers and require neurologists or physician with training and expertise in cerebrovascular disease for the medical director position at a Level II;
- Extend the allowance for a rehabilitation consult from 24 hours to 48 hours;

- Add "or attending physician" to hospitalist medical staffing requirement for Level IV centers (this requirement was subsequently deleted by the department);
- Modify definition for telemedicine;
- No additional changes were proposed to align Missouri regulations with The Joint Commission Primary Stroke Center (PSC) certification standards for Level II centers. Those from PSCs requested to meet with department representatives to explore how best to conduct and coordinate reviews; and
- Maintain four levels for stroke centers.

Out-of-Hospital

The discussion points for this group are shown in Attachment 4. Time was spent reviewing the Department's authority to promulgate the transport protocols as regulations and the need to have clear transport directives in place so stroke and STEMI patients are transported to "the right place, in the right time, for the right care". Those within the group expressed concern that the transport protocols as drafted were too prescriptive and would be difficult to keep up-to-date through a regulatory process. After much discussion, it was agreed that the guidelines that classified stroke and STEMI patient into groups based on the severity and timing of symptoms would be maintained as guidelines. This will allow those guidelines to be modified in a timely manner as the changes in best practices and evidence-based approaches warrant.

The transport protocol would be promulgated as a regulation. General language was identified to direct each patient—based on their classification group—to the level of facility best suited to meet that respective patient's needs. The out-of-hospital personnel met with both the stroke and STEMI groups to review and discuss the classification guidelines and transport protocols. For stroke, the three groups defined included 1) those within the lytic therapeutic window, 2) those in the potential window, and 3) those out-of-the-therapeutic window. For STEMI, the two groups defined included 1) those within the PCI window and 2) those outside the PCI window. The classification guidelines define the time frames and symptoms in order to categorize the stroke and STEMI patient into one of the groups. Both protocols include language that acknowledges regional plans and, where appropriate in bi-state regions, the need for out-of-state transport.

TCD Stroke and STEMI Work Groups

The balance of the day was spent reviewing the proposed plans for the Professional Education, Public Education and Quality Assurance Work Groups. Sign-up forms were made available and participants were encouraged to sign up for the group(s) in which they were interested. The Department stated that these forms would be put on-line for access by others that would like to participate. The Public Education Work Group, lead by Liz Deken and Anita Berwanger began work on their initial activities and highlights from that discussion are found on Attachment 5. Activities of the work groups will begin in 2010.

Attachment 1
Stroke and STEMI Meeting Highlights
November 17, 2009

Summer and Fall 2009 Activities & Outcomes
Time Critical Diagnosis System Partners and Missouri Department of Health and Senior Services

Date	Activities	Outcome
SYSTEM DESIGN		
June 22-25, 2009	• Statewide Trauma Consultation from American College of Surgeons-Committee on Trauma (ACS/COT). Meeting hosted by DHSS for Missouri trauma stakeholders and ACS/COT (national panel).	• Report with recommendations for Missouri's trauma arm of the Time Critical Diagnosis System. Recommendations cover broad array of system functions that included injury epidemiology, statutory authority and rules, leadership, plan, lead agency, financing, prevention, EMS, definitive care facilities, system coordination and patient flow, rehabilitation, state registry, evaluation and research. Select recommendations apply to stroke and STEMI system issues.
REGULATIONS & PROTOCOLS		
September 2008-March 2009	• 7 statewide meetings (average attendance=130)	• Final implementation plans, first drafts of regulations and protocols
July 21, 2009	• STEMI meeting in Jefferson City	• STEMI regulation/protocol review
July 22, 2009	• Stroke webinar	• Stroke protocol review • Perfected webinar approach
August 6, 2009	• STEMI meeting in Jefferson City	• STEMI regulation/protocol review
August 12, 2009	• Stroke meeting	• First round review of stroke regulations
August 21, 2009	• E-mailed draft of regulations for comments to work groups	• Specific input on both sets of regulations
September 2 & 3, 2009	• STEMI and stroke webinars	• Decisions on first section of regulation
September 14, 2009	• STEMI and stroke webinars	• Final input on regulations
September 15, 2009	• STEMI webinar	• Protocol/regulation discussion
September 21, 2008	• E-mailed revised draft of regulations to all on list serve (over 400)	• Regulation distribution
September 28, 2009	• STEMI webinar	• STEMI protocol discussion
September 29, 2009	• Regional Meeting-Jefferson City	• Regulation overview
September 30, 2009	• Regional Meeting-Cape Girardeau	
October 1, 2009	• Regional Meeting-St. Louis	
October 5, 2009	• Regional Meeting-Kirksville	
October 6, 2009	• Regional Meeting-Kansas City	
October 7, 2009	• Regional Meeting-Springfield	
September 28-October 19, 2009	• DHSS-on-line survey for people to provide comments (44 responses)	• Regulation satisfaction indication
October 26, 2009	• STEMI webinar	• STEMI protocol Discussion
November 2, 2009	• STEMI webinar	• Finalized protocols
November 17, 2009	• Statewide Stroke/STEMI Meeting	• Finalize decisions on regulations and protocols

Attachment 2
Stroke and STEMI Meeting Highlights
November 17, 2009

On-Line Survey Results for Proposed Stroke and STEMI Regulations
November 2009

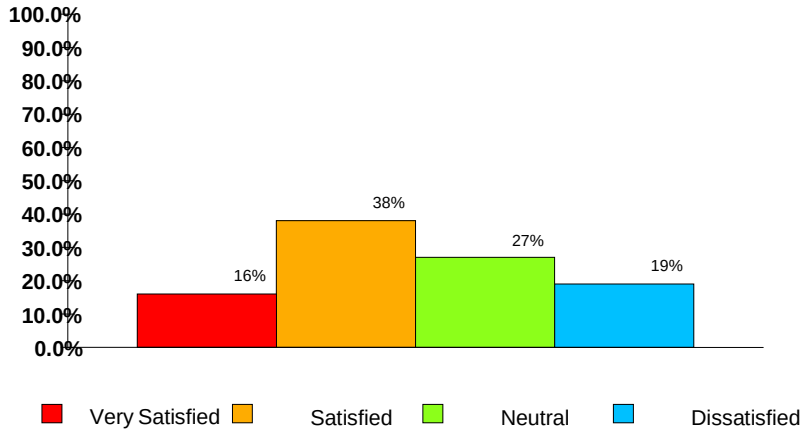
On-Line Survey Time Frame: September 28, 2009 through October 19, 2009

How Promoted:
1. On DHSS website
2. Two emails sent to over 500 people who attended or participated in process
3. Promoted at six regional meetings
4. Partner groups helped promote

Number of Respondents: 42 (33 attended regional meetings)

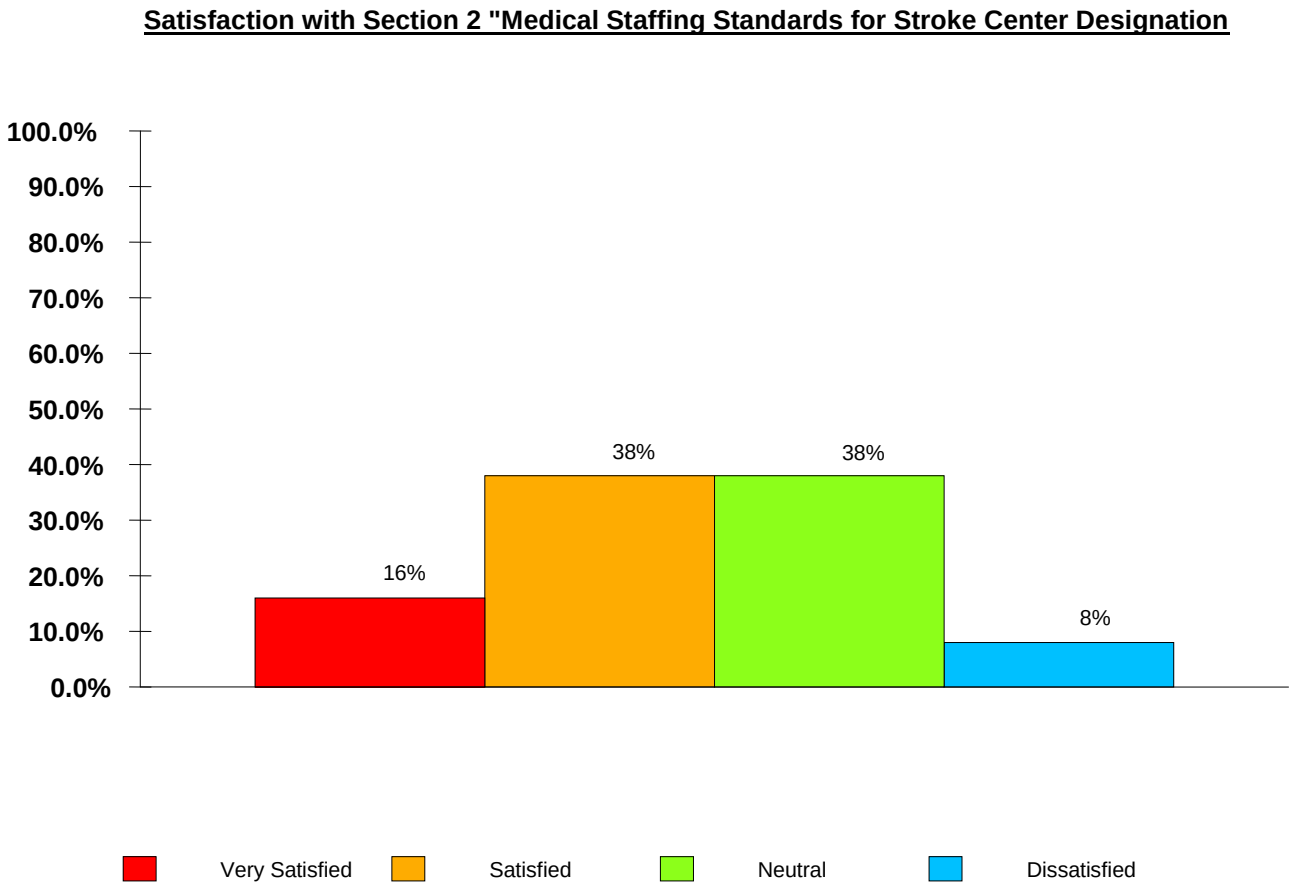
STROKE REGULATIONS

Satisfaction with Section 1 "General Standards for Stroke Center Designation"



Summary of comments-Stroke Section 1-General Standards (8 people commented)

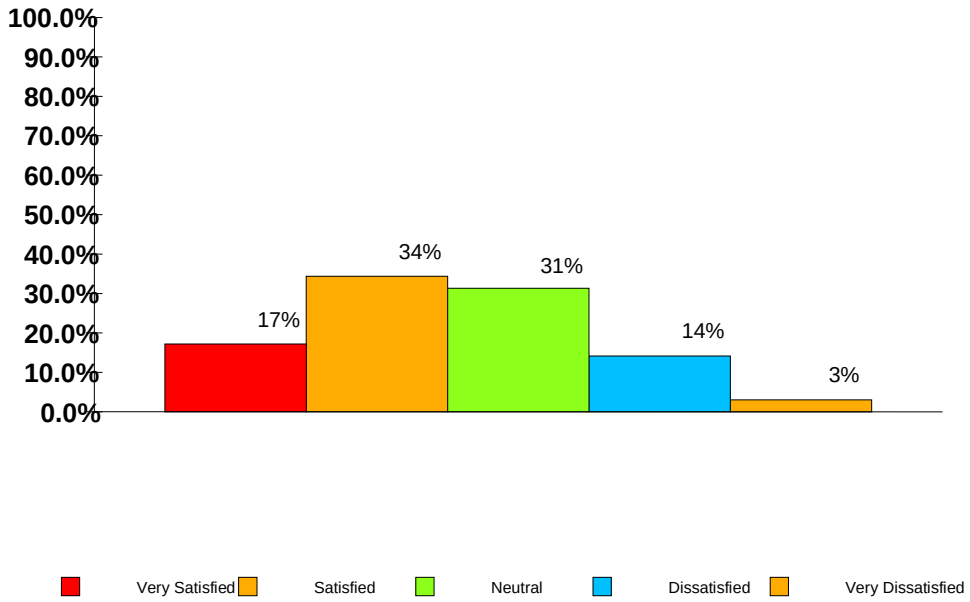
- Three people expressed concern regarding the number of hours of CME and continuing education required. Too costly and this stipulation is not quantified in the Joint Commission (JC) accreditation standards for Primary Stroke Centers (PSC).
- Should not require the Medical Director at Level II to be neurologist since other types of physicians may be qualified for this position.
- Want consistency between these standards and JC standards for PSC. (3 comments)
- The registry should be the same requirements we have for Get with the Guidelines so work is not doubled.
- Consults for physical medicine and rehab should be done within 48 hours, not 24 hours. (CHANGE MADE)
- Requested clarification on stroke patient log requirements.
- The American Heart Association feels that hospital designations within a Stroke System of care should utilize a 2 tiered approach: Primary Stroke Center (PSC) designated facilities, and Non-PSC, Acute Stroke Care Capable (ASC) facilities, in accordance with American Stroke Association recommendations.
- A large group of statewide experts worked for months studying national guidelines and discussing what could work best in Missouri. Thus is a good section.
- There are too many classifications of Stroke Center. The level IV needs to be removed.
- Do not like use of term credentialing for nursing staff.



Summary of comments-Stroke Section 2-Medical Staffing Standards (7 people commented)

- Need clarification between the two descriptions of a neurologist in Section 1 compared to Section 2. The requirement for board certified neurologists is restrictive. Difficult to recruit. Must assure that this level is absolutely necessary to maintain standard of care if another professional certification could also meet best practice standard.
- The need for the neuro-interventional specialist at a level I makes it real hard for any hospital except the large teaching hospitals to be a level I
- CME time requirement too costly for facilities. Too much stroke-specific education required for Level 2 for emergency department physicians and emergency dept. & ICU nurses. Do not like specific details spelled out.
- Content decisions were made by a large group of Missouri clinicians and experts with knowledge of the latest national guidelines and discussions. Content is good.

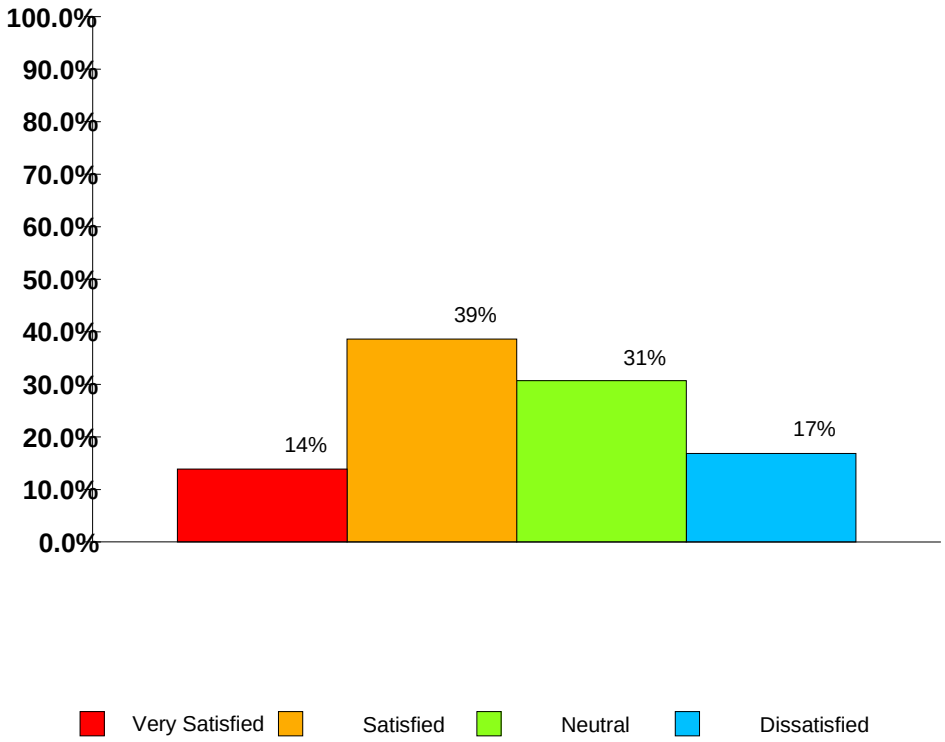
Satisfaction for Section 3:"Standards for Hospital Resource and Capabilities for Stroke Center Designation"



Summary of comments related to Stroke Section 3 –Hospital Resources and Capabilities (9 people commented)

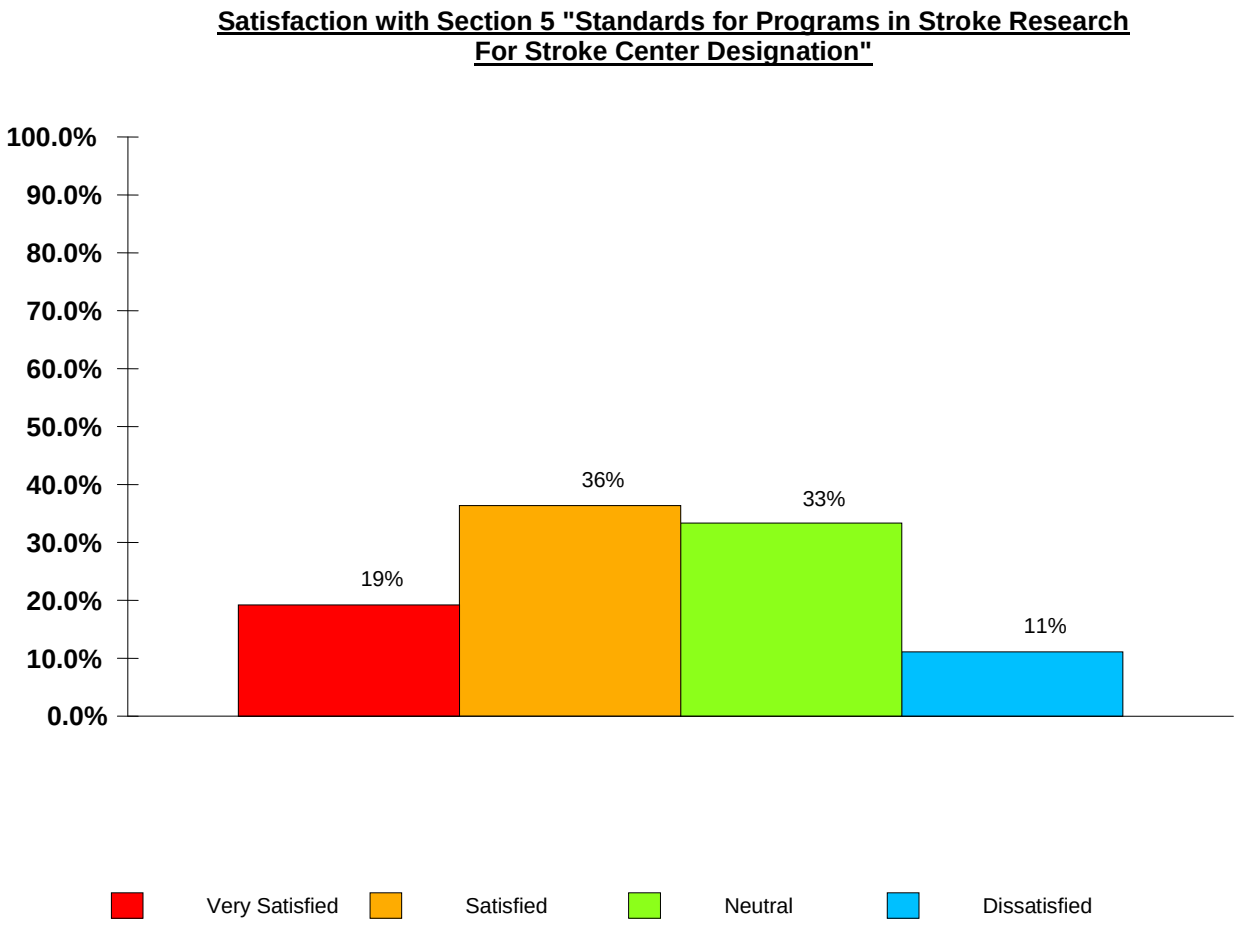
- Too many hours required for continuing education. (5 people)
- Need clarification on policies: 1) defining the relationship between emergency dept. physicians and other physician members off the stroke team and 2) “a physician who is not the emergency dept. physician shall be on duty in the ICU or available 24 hours a day"
- Currently, definitions for standards have been “harmonized” by the Joint Commission, CMS, and the American Heart Association’s (Get with the Guidelines). How will the Missouri registry be aligned with these consensus guidelines? In addition how will we be able to extract data, and maintain the integrity of the analysis of the data if definitions are not consistent? To follow yet another requirement in data reporting speaks to creating additional administrative cost and duplication of effort in a climate where we can ill-afford to further stretch resources.
- Very good work. Using national guidelines as the core, a large group of experts worked for months to draft regulations specifically designed for Missouri.

Satisfaction with Section 4: 'Standard for Hospital Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs for Stroke Center Designation'



Summary of comments related to Stroke Section 4- Standards for Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs (9 people commented)

- Our quality improvement program can capture all these reporting requirements. Want to coordinate so existing data systems can be used and we avoid duplicate data entry to populate state registry. (5 comments)
- The data is very important, we should QA the data. Need to make sure we benchmark on national as well as state level.
- Recommend CT and MR technologists availability stipulations match PSC standards.
- Feedback to EMS within 72 hours is unrealistic. Some patients are still being diagnosed and/or still hospitalized. Feedback is good, though.
- Good work on this section.



Summary of comments related to Stroke Section 5-Stroke Research (4 people commented)

- Too vague. This is too undefined.
- Again there appears to be little recognition in these regulations of other national certification and standards already in place. The restrictive nature has the potential of stifling innovation and creative approaches to patient care. The proposed regulations step over the line in allowing independent judgment to be trumped by a specific practice requirement.
- National recommendations and Missouri expert's discussion are obviously the basis for this well crafted section.

Additional comments on the Stroke Center Designation Regulations (15 people commented):

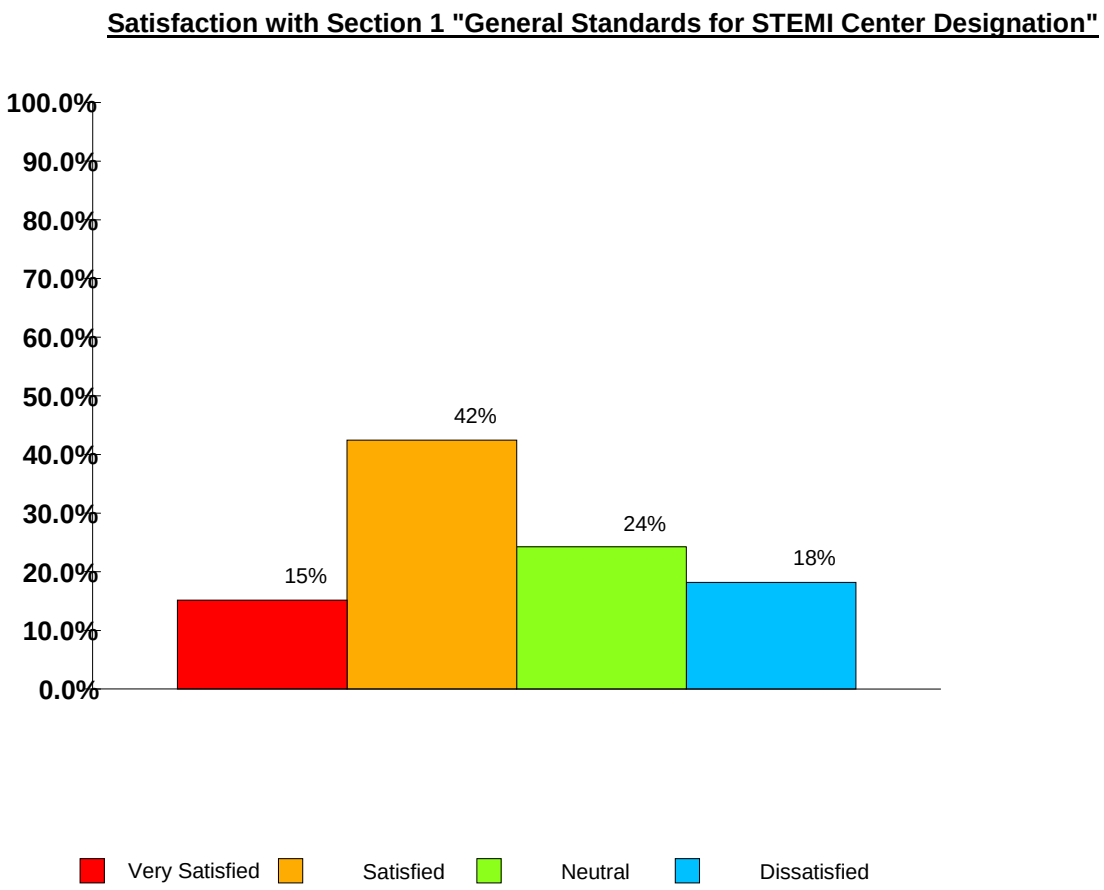
1. Want alignment of PSC and Level II centers.
2. Please make sure that protocols are evidence based and not driven by conflicts of interest from those who have financial stakes in performing interventional procedures. Don't want to divert care away from level two or three centers which are capable of delivering tPA and would be able to do so much earlier in the clinical course. Time is brain and delaying delivery of care should not be acceptable.

3. Great job
4. Throughout this two year process, over 400 experts from around our state participated in all-day meetings. I was there, and I was impressed by their diligent use of national guidelines and recommendations, their discussions about what will work best in Missouri, and their continual focus on a TCD system designed to improve patient outcomes in Missouri. The regulations are an excellent product of the hard work of dedicated professionals volunteering their time to benefit all Missourians.
5. Worthy goals and the structure seems beneficial, the transportation system away from rural areas is not sufficient to support this program outside urban areas. And while it provides options to help rural facilities support the program the costs associated with initiating and maintaining are likely over time to be greater than the benefits provided especially as patients are directed away from these facilities to ones in the metro area.
6. I strongly believe that the legislative intent in the statute was that the local medical director be responsible for creating the applicable time critical diagnosis protocols for their service. It is appropriate for DHSS to develop and reference Time Critical Patient Routing Plans that do not include prescriptive assessment and treatment modalities. I believe that time critical diagnosis protocols should not be referenced in regulation. As the science on time critical diagnosis will likely change over time and further research, referencing the protocols in regulation could result in patients being treated in a manner that does not reflect current treatment recommendations which could place the State of Missouri in a position of liability. Additionally any referenced document could legally carry the weight of regulation, and thereby become mandated rather than guidance only. Guidelines should be general in nature, not specific to a certain medication or treatment modality. New studies are being done daily which lead us to significantly different conclusions than we currently believe may appropriate. State guidelines should establish the minimum standards not the optimal expectations across a state with a mix of urban, suburban and rural communities. (8 comments, Mid America Regional Council for Emergency Response [MARCER] endorsed)
7. I am an EMS person, so I will leave the comments to the hospitals.
8. I have concerns that the proposed changes would mandate statewide protocol on areas that already have a well defined policy regarding these issues. The ability to change protocol as the science changes is extremely important. No protocol for EMS should be implemented by law, but rather through the established system of regional effort and the service Medical Director. The Bureau of EMS can, and should, provide guidelines to be used, but placing specifics in law isn't a good idea.
9. The physician CME requirements need to be balanced between Trauma, Stroke and STEMI.
   There are too many hours of CME for physicians. At a hospital that is a trauma center, stroke center and STEMI center the ED doc would have to have 24 hours per year of CME in these three areas...but this is plain too many!

Comments you have regarding Stroke Definitions (5 people commented, 3 were the same as Number 5 in the above section):

- Provided official definition for Telemedicine from American Telemedicine Association (ATA). (Changed to ATA definition.)
- Well done.

STEMI REGULATIONS

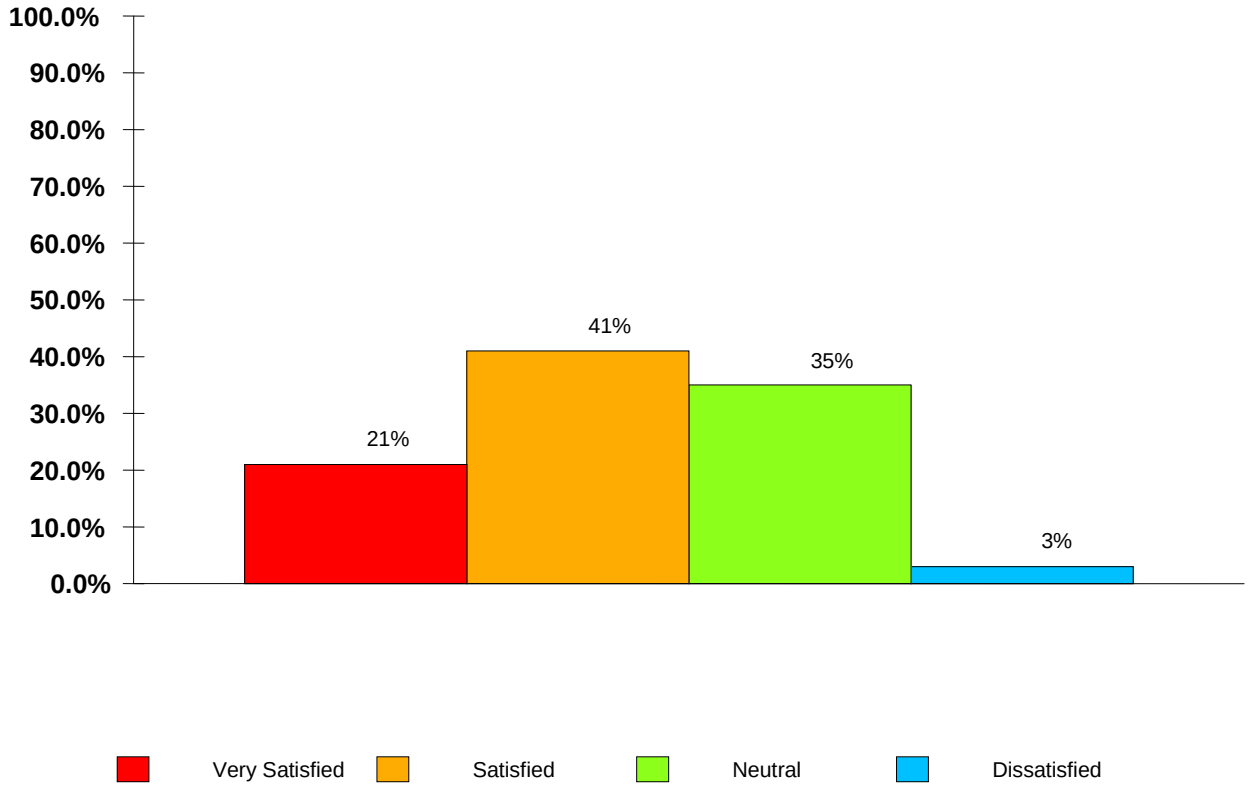


Summary of comments related to STEMI Section 1-General Standards (9 people commented)

- I feel that more emphasis should have been placed on actual outcomes versus the 36 primary PCIs. I feel that the volume rule exception should NOT preclude more than one hospital in a community from achieving the rule exception. I am unclear as to how a hospital that is designated a Level III can ever hope to attain a Level II. Would there be an allowance for an institution that plans to invest heavily in their CV program in order to upgrade?
- The STEMI task force recommended the STEMI centers meet volume requirements, it is unfortunate there was an out given to the level II's. There is also some concern with the term 'near' in a hospital that is near but not at... If exceptions are going to remain for level II's then these same exceptions should apply for level I's.
- The American Heart Association feels that hospital designations within a STEMI System of Care should utilize a 2 tiered approach: STEMI receiving (PCI capable) and STEMI referring (not PCI capable), in accordance with AHA Mission: Lifeline Criteria.
- Provided additional extensive detail regarding care standards, e.g., primary PCI availability in receiving hospital, cardiac catheterization lab stipulations, and competence standards for interventional cardiologists.
- As with the Stroke Regulations, the degree of minutia begins to encroach on best practice judgment by skilled practitioners.
- Well done. Draft accomplished by much open large group discussion and study of national recommendations.

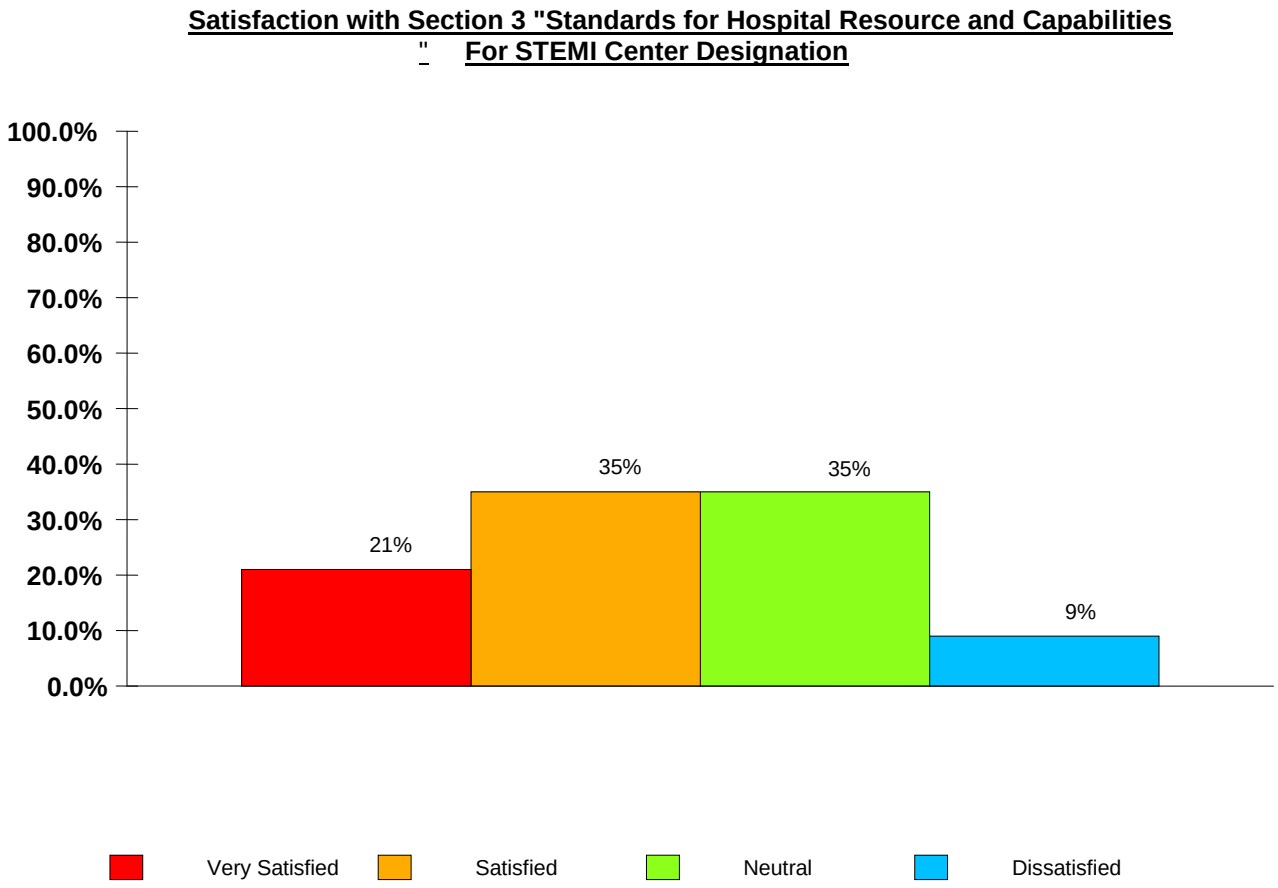
- There are too many classifications of STEMI Center. The level IV needs to be removed. In reality all facilities have the capability to refer patients to those facilities with enhanced capabilities. Excessive division complicates decision making schemes.
- Need to drop the expectation from 95% in (1)(F)3.F to 75% to match ACC guidelines/recommendations.
- Level I institutions need procedures in place to institute therapeutic hypothermia.
- Credentialing is mainly used for Physicians and would require a new system set up for the credentialing of nursing staff. The hours of required "yearly" education for all the staff members caring for the TCD patients can be a burden on the hospitals.

Satisfaction with Section 2 "Medical Staffing Standards for STEMI Center Designation



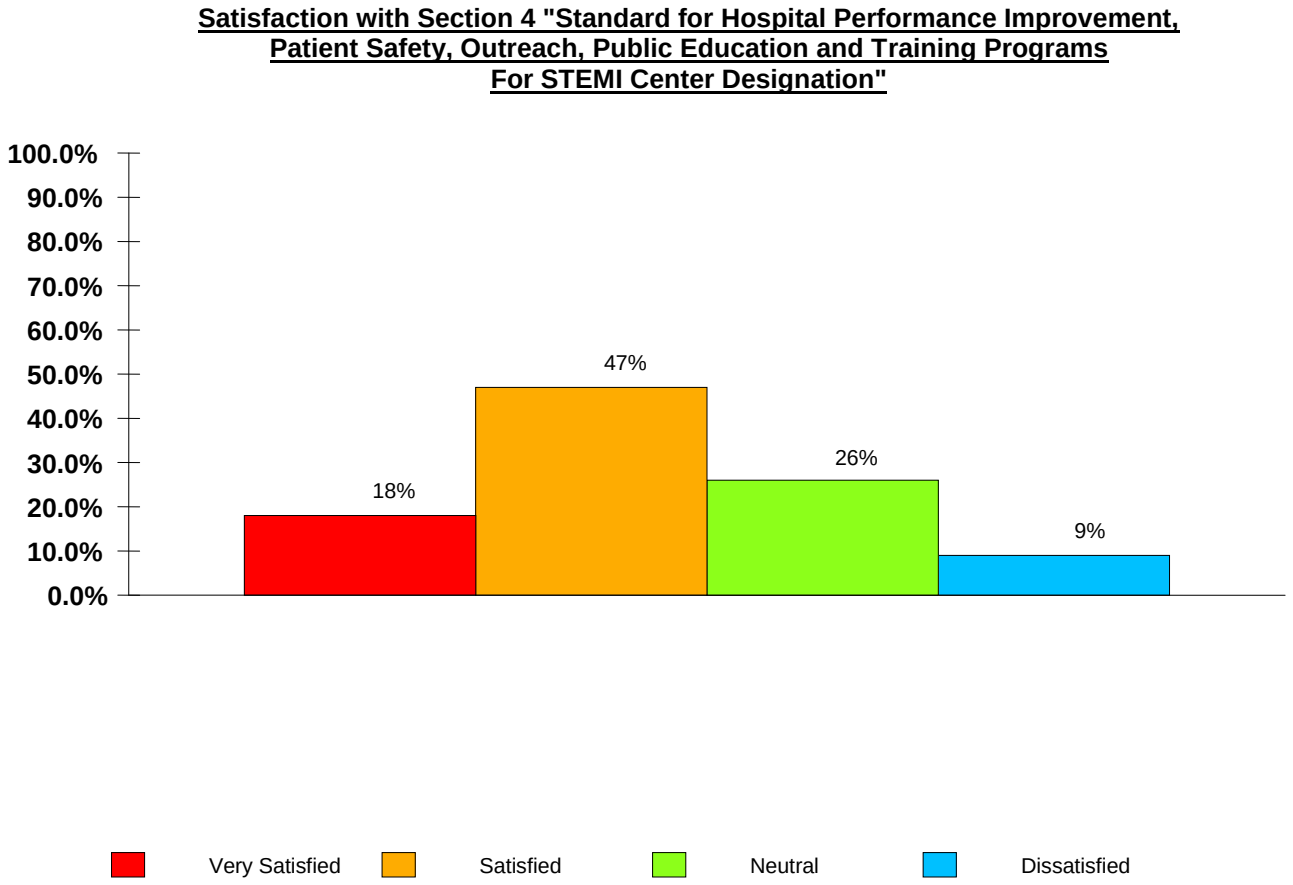
Summary of comments related to STEMI Section 2-Medical Staffing Standards (5 people commented)

- CME time requirement too costly for facilities
- Too much focus on cardiology and not enough on emergency medicine - that appears to be very much subordinate to cardiology instead of being co-directors (without ED buy in this will not work)
- Regulations once again appear to be too restrictive in their personnel requirements. Requiring a board certified interventional cardiologist versus a cardiologist raises the question about whether this requirement improves best practice and quality of care.
- Good work. Many hours of large group discussion in an open forum focused national recommendations and what could improve patient outcomes in Missouri. Well-done section.



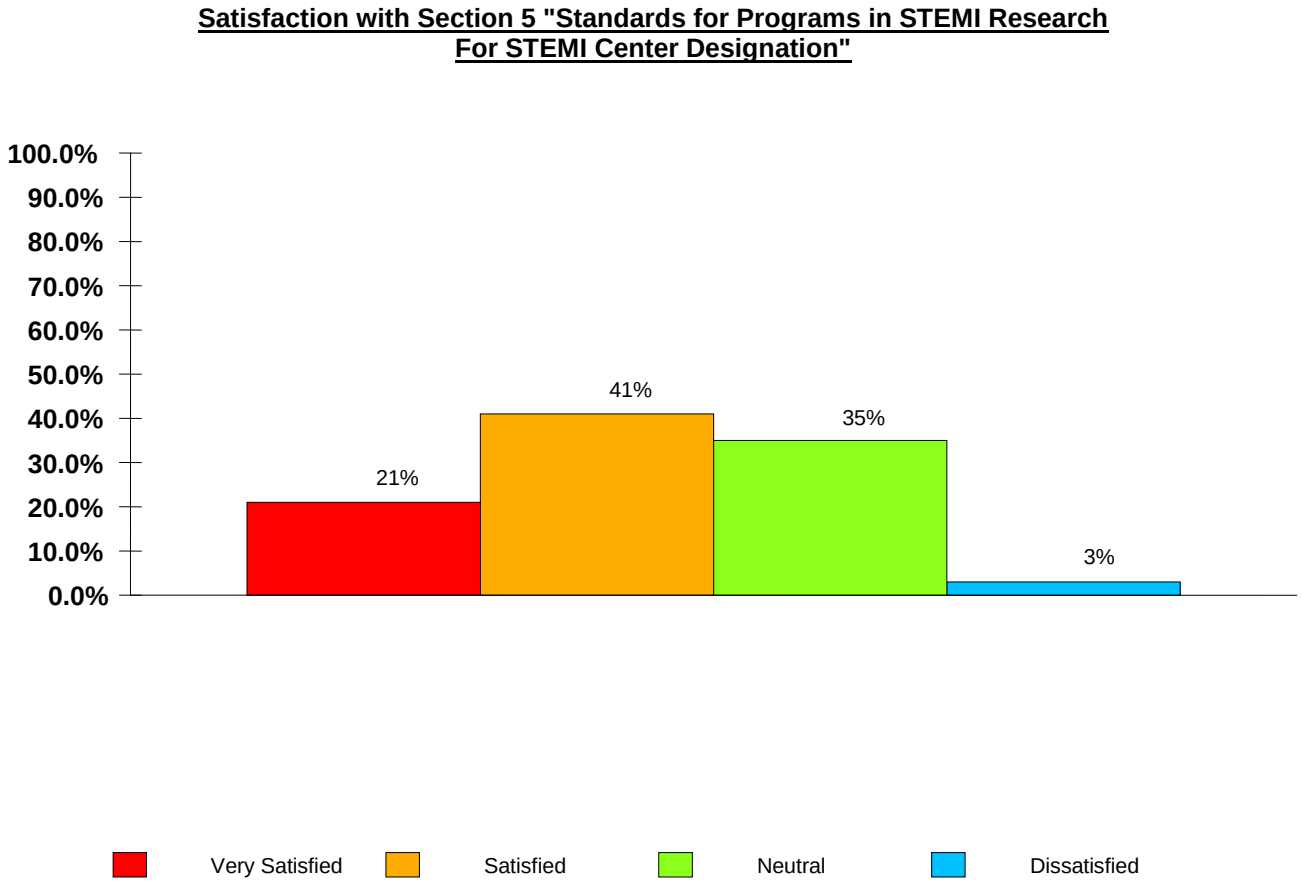
Summary of comments related to STEMI Section 3-Hospital Resources and Capabilities (7 people commented)

- CME time requirement too costly for facilities (2)
- Need to emphasize emergency department capability and cardiology-ED interaction
- The extreme detail throws a barrier in front of those individuals who would and should be able to use independent judgment without sacrificing high standards. Identifying outcomes, evaluation practices and continuous quality improvement, must be part of the regulatory formula.
- Well done.



Summary of comments related to STEMI Section 4- Hospital Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs (4 people commented)

- We recommend Action Registry Get With the Guidelines for the purpose to report data and compare to national guidelines. The national data point measurements are the ones being pushed by the American College of Cardiologist and the American Heart Association.
- Coordination and training of community transport personnel and education will be critical in the implementation of these regulations.
- Well done.
- There needs to be a way to use the current data collection process we use (not requiring data to be also placed into the state data base) thus the data could be benchmarked nationally not just in the state of Missouri.



Summary of comments related to STEMI Section 5-STEMI Research (2 comments)

- Well done. Much large group discussion about national recommendations and what would be best for patient care in Missouri.

Additional comments on the STEMI Center Designation Regulations (13 comments)**:**

1. Too much emphasis on PCI only, data still shows that PCI will not be close to universally available despite what cardiologist think (they don't appreciate the logistical barriers to pulling this off).
2. The regulations should be reviewed for balance between overly restrictive regulations and best practice standards. The regulations appear to overlook national certification and best practice standards that are currently in place such as those from the Joint Commission, CMS, AHA and others.
3. This document is the product of many respected clinicians and experts from around the state who volunteered their time to craft the very best TCD STEMI System for Missouri. They continually reminded each other to move away from the siloed interests of their particular modality or employer and to design a system using national guidelines, focusing on what can work in Missouri to improve overall STEMI patient care.
4. The physician CME requirements need to be balanced between Trauma, Stroke and STEMI and not be too many.
5. I believe strongly that the legislative intent in the statute was that the local medical director be responsible for creating the applicable time critical diagnosis protocols for their service and then submit then to the

Missouri Bureau of EMS for approval. It is appropriate for the Bureau to provide guidelines to the local medical director pertaining to assessment, triage and transportation. 2. I believe that time critical diagnosis protocols should not be referenced in regulation. As the science on time critical diagnosis will likely change over time and further research, referencing the protocols in regulation could result in patients being treated in a manner that does not reflect current treatment recommendations which could place the State of Missouri in a position of liability. 3. Guidelines should be general in nature, not specific to a certain medication or treatment modality. As new studies are being done daily which may lead us to significantly different conclusions than we currently believe appropriate. State guidelines should establish the minimum standards but not the optimal expectations across a state with a mix of urban, suburban and rural communities. (7 comments, MARCER endorsed)

Comments regarding STEMI Definitions. (4 comments)

Three were the same as comment number 5 from STEMI additional comment section; the other stated "well done".

Attachment 2—On-Line Survey Results
Stroke and STEMI Meeting Highlights
November 17, 2009

Other Information:

Number of TCD meetings attended by respondents:
(N=40)

Number of meetings attended	Number	Percentage
None	5	13%
1-3	19	48%
4-6	4	4%
7 or more	12	30%

Position held by respondent
(N=39)

Positions	Number	Percentage
EMS	12	31%
Hospital Administrator	7	18%
Physician	8	21%
Nurse/Nurse Practitioner	6	15%
Other	6	15%

Number working for a hospital:
(N=40)

Work for a hospital	Number	Percentage
Yes	19	48%
No	21	53%

Responders whose hospital Intends to apply for center designation
(N=20)

Hospital Intends to Apply	Number	Percentage
No	3	15%
Yes	11	55%
Not Sure	6	30%

Stroke Center Designation (N=9)	Number	Percentage	STEMI Center Designation (N=8)	Number	Percentage
Stroke Level I	3	33%	STEMI Level I	3	38%
Stroke Level II	4	44%	STEMI Level II	5	63%
Stroke Level III	1	11%	STEMI Level III	0	
Stroke Level IV	1	11%	STEMI Level IV	0	

Attachment 3—Proposed Stroke and STEMI Regulation Discussion Points
Stroke and STEMI Meeting Highlights
November 17, 2009

Proposed STEMI Regulation	Comments received	Change/Rationale	Discussion Issue
Section 1 - General Standards for STEMI Center Designation			
1. Page 2, (D) Cardiac Cath Lab	• No comments	• 75 PCIs per physician is recommendation only, cannot enforce recommendations. Did slight edits on language to make clearer.	• Should we keep recommendation?
2. Page 3, (F) Level II criteria	• Wanted alternative for those hospitals that were close but did not meet volume standard • Wanted more emphasis on outcomes as opposed to PCI volumes • 'Near but not at' needs clarification	• Modified this section to make language clearer for alternative criteria for those that do not meet the 36 primary and 200 elective PCI volume criteria. • Must meet at least one standard, either 36 primary OR 200 elective • If don't meet 36 primary PCI volume, then each operator should conduct at least 11 PPCI/year or receive oversight • If don't meet 200 elective PCI volume, then each operator should conduct at least 75 PCIs/year or receive oversight • Requires facility to have on-site surgical services • Requires facility to demonstrate that has PCI D2B process that is better than average performance measure standard since hospital conducts fewer procedures. • Requires facility to be comparable to state or national outcomes and benchmarks since conducts fewer procedures. • Need to define "near but not at"	• Any recommendations for this alternative language for Level II STEMI centers? • What is recommendation for minimum number of Elective PCIs if institution conducts 36 PPCIs, but <200 elective PCIs? • What is recommendation for minimum number of Primary PCIs if institution conducts >200 Elective PCIs but <36 PPCIs?
3. Page 4, (H) STEMI Medical Director	• Too many CMEs required, too costly.	• Clarified language so similar with general wording in stroke language. • Maintained number of CME requirements for the position • Eliminated the requirement for conference attendance for Level III and IV	• Should CME requirement be altered?
4. Page 4, (I) STEMI Program coordinator/manager	• Too many continuing education hours required, too costly	• Clarified language so similar to stroke • Maintained number of hours • Eliminated annual conference requirement for managers at Level II and IV.	• Are DHSS modifications acceptable?
5. Additional requirement for Level I	• Require provision for therapeutic hypothermia	• Recent evidence is indicating therapeutic value of this procedure.	• Should this be requirement for Level Is?
Section 2- Medical Staffing Standards			
6. Page 6, (B) 4. ED Physician	• Don't require specialty training in emergency medicine	• DHSS made change since there are a multitude of routes to become ED physician and hospital can assure credentials	

Attachment 3—Stroke and STEMI Regulation Discussion Points
Stroke and STEMI Meeting Highlights
November 17, 2009

Proposed STEMI Regulation	Comments received	Change/Rationale	Discussion Issue
7. Page 6, (B) 6. Hospitalists	• Don't specify physician type	• DHSS remove example	
Section 3 - Hospital Resources and Capabilities			
8. Page 7, (A) 1. ED staffing	• Too many continuing education hours required, too costly	• Decreased CMEs: Level I & II - 6 hours/year, Level III & IV- 6 hours every other year • Made same reductions for RNs • Separated requirement for 24 hour availability from CME requirement in order to clarify both	• Does group agree with DHSS changes
9. Page 8, (A)1.G ED Written Care Protocols		• Clarification done in wording	Any other clarifications needed?
10. Page 9, (A)2.J ED Equipment		• Clarified and changed parenteral fluids and blood to resuscitation fluids.	
11. Page 10, (C) Cardiac Cath Lab, 12. Page 11 (E) Operating room		• Clarified language	
13. Page 11, (G) Laboratory	• Change to align with trauma regulations	• Added blood bank or access provision for Level IV hospitals so aligns with current Level IV Trauma Proposed Regulations	
Section 5 - Research			
14. Page 12, (A)		• Reorder research examples to be in same order as given in stroke regulations	
Definitions			
15. Page 2, (X) Phase I cardiac rehabilitation	• Add definition	• Proposed definition added	• Agree with definition added?
General Comments			
16. Number of levels of STEMI centers	• AHA recommends that have only two levels - receiving and referring hospitals • Some recommend that delete the fourth level	• Group consensus is reflected in the four levels, which generally translates to two levels of receiving hospitals and two levels of referring hospitals and is reflective of the differing capacities of Missouri hospitals.	• Does group affirm current four levels?
17. General vs. Specific	• Some wanted more specific detail, some wanted less	• DHSS worked for appropriate balance and made modifications in 11/17/09 version where core standards were not compromised based on current evidence base	

Attachment 3—Stroke and STEMI Regulation Discussion Points
Stroke and STEMI Meeting Highlights
November 17, 2009

Proposed Stroke Regulation	Comments received	Change/Rationale	Discussion Issue
Section 1 - General Standards for Stroke Center Designation			
1. Page 2:(C)2.-Continuing education for stroke call roster E. Level I - 10 hours continuing education every year F. Level II - 8 hours every year G. Level III & IV 8 hours every other year	• Too many hours, too costly	• Clarified language • Recommend that hours stay the same o Corresponds with recommendations made by Brain Attack Coalition (BAC) recommendations o Consensus from work group discussions o Eliminated requirement for annual conference attendance for Level III & IV facilities.	• Should requirements be changed?
2. Page 3. (D) Stroke Medical Director requirements	• Recommended that neurologist not required at level II	• Work group discussions has broadened language for allowances for Level II Medical Director--"board certified or board admissible physician with training and expertise in cerebrovascular disease." Grandfather those in position at time regulations go into effect	• Verify that modification acceptable
3. Page 4. (E) Stroke program manager/coordinator-continuing education requirements 2. Level I - 10 hours/year 3. Level II - 8 hours/year 4. Level III & IV - 8 hours every other year	• Too many hours, too costly	• Clarified language, made language more consistent with STEMI regulations. Do not require managers to attend national, state or regional conference at Level III and IV facilities. • Recommend that hours stay the same, same rationale as outlined in Item number 1.	• Are changes acceptable?
4. Page 5. (K) Rehabilitation Consult	• Allow more time	• Extended time frame to 48 hours as recommended	• Verify that modification addresses recommendation.
5. Page 6. (P) Diversion Protocol		• DHSS made consistent with other language	
Section 2- Medical Staffing Standards			
6. Page 6, 5. Emergency Department	• Don't require specialty training in emergency medicine	• DHSS made change since there are multitude of routes to become ED physician and hospital can assure credentials	
7. Page 6, 7. Hospitalist (IV)	• Don't specify physician type	• DHSS removed example	
Section 3 - Hospital Resources and Capabilities			
8. Page 7, (B) & (C) Emergency Department Physician	• Too many CMEs	• Decreased CMEs Level I & II - 6 hours/year Level III & IV - 6 hours every other year • Same continuing education changes for RNs	• Does group agree with DHSS changes?

Proposed Stroke Regulation	Comments received	Change/Rationale	Discussion Issue
		• Separated requirement for 24 hour availability from CME requirement to clarify	
9. Page 7, ED equipment and Page 10 (E) Operating room equipment		• Clarified language. Changed: Thermal control equipment for patients, ~~parenteral fluids and blood~~ and resuscitation fluids~~,~~	
10. Page 10, (G) 5.--added blood bank or access provision for Level IV hospitals	• Change made to align to Trauma Center-Level IV recommendations	• DHSS made change	
Definitions			
11. Page 3, (II) Telemedicine	• Recommended definition from American Telemedicine Association	• Adapted language from Association's webpage definitions	• Does group agree with DHSS adaptation?
General Comments			
12. Joint Commission-Primary Stroke Center (PSC) linkage with Level II Stroke Centers	• Recommendation to fully align PSC with Level II Stroke Center Designation Standards	• DHSS has compared the PSC certification standards to Level II standards and found them generally in alignment • The work group has aligned Missouri standards with PCS standards. • Differences occur due to need to provide clear standards in Missouri regulations against which centers are evaluated. PSC Certification process focuses on general policy and process issues. For example, Missouri reviewers look at specific amount and type of continuing education conducted whereas the Joint Commission reviewers assure that there is a process in place to assure that stroke staff receives stroke education. Missouri standards are from BAC. • DHSS would be happy to meet with representatives from the 11 PSC in Missouri if further discussion is needed.	• Are there any specific recommendations needed for the regulations to better align with Joint Commission standards?
13. Number of Levels of Stroke Centers	• AHA recommends 2 levels-receiving and referring • Some recommend 3 levels	• Group consensus is reflected in the four levels, which generally translates to two levels of receiving hospitals and two levels of referring hospitals.	• Does group affirm current four levels?
14. General vs. specific	• Some want more specific detail--some want less detail	• DHSS worked for appropriate balance and made modifications in the 11/17/09 version where core standards were not compromised	

Attachment 4— Out of Hospital Discussion Points
Stroke and STEMI Meeting Highlights
November 17, 2009

Item	Name	Issue	Discussion Question
BOTH			
Plans for Resource Guide		• Will protocols be put in regulation? • Want ability to update easily as best practice changes	• What is best approach for updating?
Allowance for Regional Modification		• Want assurance of ability to modify based on regional differences	• Is current explanation on cover of manual sufficient?
STEMI			
3.2 STEMI	Field Triage Protocol	• Clarify language in response to STEMI at step 3. Current language is confusing Possible alternative: PCI Window = 120 minutes from EMS medical contact to reperfusion (PCI) Lytic Window = 30 minutes **Group I: Take to closest Level I or II STEMI center** • If within PCI window, • Chest pain greater than 12 hours duration or • Thrombolytic ineligible **Group II: (outside PCI Window) Take to closest STEMI center** • If outside PCI window but within lytics window • if taken to Level III or IV center, they will evaluate for lytic therapy and/or rapid transfer to higher level center	• What is proposed alternative language? • **Review Draft of Proposed Transport Protocol**.
3.3 STEMI	EMS Guidelines	• Deleted specific reference to O_2 administration since sufficiently addressed in item number 1. This was primarily holdover from guideline for stroke patient and believed not needed as part of STEMI guideline. • Deleted reference to left arm for IV • Modified language regarding nitro administration	• Any concerns with this deletion? • Any reason why left arm is better? • Is modification OK?
3.4 STEMI	Inter-facility transfer (not on lytics)	• Added language to emphasize importance of not delaying transport waiting for hand-off information	• Modification OK?
3.5 STEMI	Inter-facility transfer (on lytics)	• Added same language as on 3.4 • Need clarification regarding recommendation on whether nursing staff may need to accompany patient during inter-facility transport	• Modifications OK?
STROKE			
4.3 Stroke	EMS Guidelines	• Simplified and clarified O_2 administration wording	• Modification OK?
4.4 & 4.5 Stroke	Inter-facility transfer (not on lytics and on lytics)	• Added language to emphasize importance of not delaying transport waiting for hand-off information	• Modifications OK?

Attachment 5— Public Education Highlights
Stroke and STEMI Meeting Highlights
November 17, 2009

General Comments

There was some desire to move beyond just 911 and signs & symptoms and message on WHY the patient should use 911, WHAT to expect from your experience, and encouraging patients to demand best practice. The group was advised that this is beyond our scope. The issue was raised that it will be a challenge for hospitals to message without it being seen as promoting their hospital. It was believed important to get more clarity regarding what hospitals are being required as part of their TCD Level designation to do for "community outreach".

Message:

- Why should you call 911? Because you get care more quickly
- What 911 is actually for
- Who 911 is for (it is for YOU, not just the other guy)

Audiences to Target:

- 40-50s, younger
- Rural, 50+
- Grandkids/ young people
- Workplaces
- Men (sports clubs/ Dads)
- Schools and universities
- Seniors/ AARP
- Faith leaders/ parish nurses
- African American population
- Women/ Red Hat group
- Patients with previous history

Additional Communication Channels

-Radio, PSAs, Newspaper, Social Media/ Twitter/ Facebook

Resources Needed

- Compilation of existing messages, campaigns, outreach efforts – in Missouri and beyond
- Information on communication strategies – what does and doesn't work?
- Other entities we might want to partner with on this (Such as Health Literacy Missouri) – maybe get a list of non profit health providers from MFH?
- Information on what public already knows, or what percentage of public already uses 911 (Behavioral Risk Factor Surveillance System data-BRFSS)

Logistics and Next Steps

- Webinars/ conference calls-Conference calls should be fine. No particular interest was displayed in face to face, though might try to have one more in the spring.
- Time frame for project is from now through the end of 2010 to work on this.
- Get in touch with partners doing similar messaging, collect information and data from BRFSS collected by Department.
- Wednesdays at 4:00p.m. designated for meeting time.
- The group may need to invite people who have participated to this point in TCD process, e.g., marketing and PR staff for hospitals on a list from The Vandiver Group.
- First conference call Wednesday, December 9 at 4:00 pm. (on DHSS conference line)
- Will send out group e-mail list.

Homework for group: Research existing campaigns, hospitals working on this messaging, etc. and send them to the Liz Deken or Anita Berwanger.